

B) Remarks:

Information Disclosure Statement:

It is noted that the Office Action Summary, and Attachments thereto, did not include an initialed, signed, and dated Applicant's Information Disclosure Statement (PTO-1449) filed with the originally filed application dated 01/24/2002. Please see the attached copies of Applicant's Utility Patent Application Transmittal and Applicants returned Post Card Receipt demonstrating Applicant's filing of the referenced IDS and references. The Examiner is kindly requested to review the references submitted and provide a copy of the signed, initialed, and dated Information Disclosure Statement (PTO-1449) to Applicant.

Response to Election/Restriction Requirement:

In response to the Office Action mailed April 10, 2003 on the above-identified application, please reconsider Applicant's traversal of the Restriction Requirement. Applicant's traversal is on the grounds that the species recited in the Restriction Requirement are not properly grouped. The Examiner indicated in the Office Action of April 10, 2003, "the Applicant alleges that Figures 3-8b are one species and Figures 9-13b are another species." However, the Applicant has not made this assertion. The species submitted by the Applicant are repeated here as follows:

Species	Figures	Claims Readable on Species	Pages at which Species Supported in Specification	Description of Species
Species A	1 and 2	1, 4, 7, 8, 13, 15, 16, 17, 21-26, new claims 27-32	Page 31, lines 9-16	Syringe with corrugated sheath
Species B	3 and 4	2, 5, 9, 10, 14	Page 31, lines 17-21	Syringe having straight and corrugated barrel segments
Species C	5, 6a, 6b	3, 6, 11, 12, 18, 19	Page 32, lines 3-13	Syringe having mating concentric plunger and syringe barrels
Species D	7, 8a, 8b	3, 6, 11, 12, 18, 19	Page 32, lines 14-22	Syringe having concentric syringe barrels and mating plunger member
Species E	9, 10, 11	20	Page 33, lines 3-12	Contaminant shield molded in syringe barrel cavity
Species F	12	20	Page 33, lines 13-16	Threaded end-cap contaminant shield
Species G	13a	20	Page 33, lines 17-20	End-cap with lip or flange
Species H	13b	20	Page 33, lines 21-23	End-cap without extending wall

The claims readable on each of Species A-H and the corresponding support describing each of the Species A-H, as provided by the specification, is set forth above. It is noted that claims 3, 6, 11, 12, 18, and 19 are generic to Species C and D and Claim 20 is generic to Species E, F, G, and H. Applicant respectfully requests that the Examiner kindly reconsider the original Restriction Requirement in view of Applicant's Species grouping of the original and newly submitted claims. New claims 27-32 are readable on the elected species A and contain subject matter fully supported by the originally filed disclosure.

Response to Rejections:

1. Claims 1, 4, 7, 8, 13, 15-17, 21, and 23-26 have been rejected under 35 U.S.C. 102(b) as being anticipated by Osborn, III et al., Patent No. 5,817,047.

• **Specifically regarding the rejection of claim 1:**

Initially, it is noted that Osborn, III et al. is non-analogous art. The claimed syringe of the instant invention has meaning and performs specific functions, as defined by the specification. Osborn et al. is drawn to a tampon inserter and not to a syringe. Applicant's invention is not drawn to tampons and devices used to dispense and insert tampons. The syringe of the instant invention is not used for holding or inserting tampons. In any event, claim 1 has been amended to recite that the plunger shaft has an attached piston, wherein said attached piston is capable of slidably engaging and maintaining a tight seal with the inner wall surfaces of the hollow syringe barrel cavity along the entire length of the syringe barrel cavity during withdrawal and advancement of the plunger shaft and attached piston. Note that claim 1 has been amended to recite that the plunger member comprising a plunger shaft has an attached piston. Osborn, III et al., do not disclose an attached piston. Although not recited in the rejection, the examiner appears to be relying on the tampon 20 as teaching a piston. The tampon of the Osborn, III et al. reference is not a piston and is not capable of functioning as a piston in a syringe, as claimed by Applicant. The tampon of the Osborn, III et al. reference is deposited outside the tampon inserter device during use, where it performs its intended function of absorbing liquids. The function of the attached piston of the instant invention is performed within the syringe barrel cavity and the piston does not absorb liquids. The piston of the invention is not deposited external to the syringe during use, as is the tampon in the Osborn, III et al. reference,

but remains within the syringe barrel cavity during use and remains attached to the forward end of the plunger shaft during use to perform its function.

Also, Osborn, III et al. do not disclose a plunger shaft having an attached piston that slidably engages and maintains a tight seal with the inner wall surfaces of the hollow syringe barrel cavity along the entire length of the syringe barrel cavity during withdrawal and advancement of the plunger shaft and attached piston, as recited in amended claim 1. In fact, the tampon of the Osborn, III et al. reference is not attached to the plunger shaft. Withdrawal of the plunger shaft in the Osborn, III et al. reference would leave the tampon spaced apart from the plunger shaft. In fact, the reference does not disclose that withdrawal of the plunger shaft is possible – it certainly is not warranted. Thus, the tampon does not slidably engage and maintain a tight seal with the inner wall surfaces of the tampon dispenser during withdrawal and advancement of the plunger shaft. The instant invention, however, claims an attached piston that contacts and slidably engages and maintains a tight seal with the inner wall surfaces of the hollow syringe barrel cavity along the entire length of the syringe barrel cavity during withdrawal and advancement of the plunger shaft and piston. It is noted that if the tampon of the Osborn, III et al. reference were attached to the plunger, the tampon could not be deposited vaginally as intended and, thus, would not be capable of functioning as intended.

Additionally, the Osborn, III et al. reference does not recite a corrugated sheath attached to a rearward end face surface of said syringe barrel handle member, as claimed by Applicant. The Examiner will note that the Osborn, III et al. reference discusses at column 4, lines 30-34, with reference to Figure 2, that attachment of the bellows 100 is to cylinder 50 and not to gripping means 60. Note that the limitations of Applicant's amended claim 1 require that the corrugated sheath be attached to a rearward end face surface of said syringe barrel handle member which in turn is permanently attached to the rearward end terminus of the syringe barrel.

A claim is anticipated by a reference only if each and every element as set forth in the claim is found in the reference. For these reasons, Applicant submits that Osborn, III et al. do not anticipate the claimed subject matter of claim 1. Accordingly, the Examiner is requested to withdraw this rejection.

• **Specifically regarding the rejection of claim 4:**

Claim 4 has been cancelled, the limitations of which are now included in claim 1.

- **Specifically regarding the rejection of claim 7:**

Claim 7 has been amended to depend from claim 1. The rejection of claim 7 should be withdrawn because the Osborn, III et al. reference does not recite that the plunger shaft handle member is molded to the rear terminus of the plunger shaft, as claimed by Applicant. The Examiner will note that the Osborn, III et al. reference discusses at column 6, lines 33-36, with reference to Figures 1-3, that a seal 90 is located at the rearward end terminus of the plunger 30. The seal 90 is separate from the gripping means 70. Note that the gripping means 70 is located on the longitudinal periphery of the plunger 30 and not at the rearward end terminus of the plunger 30. Note that seal 90 could not be located at the rearward end terminus of the plunger 30 if the gripping means 70 were located there. The limitation of Applicant's claim 7 requires that the plunger shaft handle member be molded to the rear face terminus of the plunger shaft -- not located on the longitudinal periphery, as in the Osborn, III et al. reference. Further, the reference does not teach that the plunger shaft handle member is molded to the rear face terminus of the plunger shaft. The Osborn, III et al. reference makes no attempt to discuss how, and if, the plunger shaft handle member is attached to the plunger shaft. A claim is anticipated by a reference only if each and every element as set forth in the claim is found in the reference. The Osborn, III et al. reference does not anticipate the limitations of claim 7. Accordingly, the Examiner is requested to withdraw this rejection.

ASSM

- **Specifically regarding the rejection of claim 8:**

The rejection of claim 8 should be withdrawn because the Osborn, III et al. reference does not recite that the corrugated sheath is *molded* to the plunger shaft handle member, as claimed by Applicant. The Osborn, III et al. reference is silent and makes no attempt to discuss an attachment relationship between the bellows 100 and the gripping means 70, or even if an attachment is present. One cannot conclude from the drawings that an attachment exists between bellows 100 and gripping means 70. The reference must recite the claimed limitation – it cannot be assumed to be present. A claim is anticipated by a reference only if each and every element as set forth in the claim is found in the reference. The Osborn, III et al. reference does not anticipate the limitations of claim 8. Accordingly, the Examiner is requested to withdraw this rejection.

- **Specifically regarding the rejection of claim 13:**

The rejection of claim 13 should be withdrawn for the reasons stated above with respect to claim 1, as claim 13 depends directly from claim 1.

- **Specifically regarding the rejection of claim 15:**

Claim 15 has been cancelled. The limitations of claim 15 are now included in claim 1.

- **Specifically regarding the rejection of claim 16:**

Claim 16 has been amended to depend from claim 1. The rejection of claim 16 should be withdrawn because the Osborn, III et al. reference does not recite that the syringe barrel handle member is *molded to or formed on* the rearward end terminus of the syringe barrel, as claimed. In fact, the Osborn, III et al. reference recites only the presence of a gripping means 60 and a tampon dispenser. The gripping means 60 is located on the longitudinal periphery of the tampon cylinder 50. The Examiner will note that the Osborn, III et al. reference discusses at column 4, lines 30-34, with reference to Figure 2, that attachment of the bellows 100 is to cylinder 50 – not to gripping means 60. Accordingly, attachment of bellows 100 to cylinder 50 would not be possible if gripping means 60 were attached to the terminus of the cylinder 50. The gripping means 60 in the Osborn, III et al. reference is located on the longitudinal periphery of the cylinder 50 and not at the rearward terminus of cylinder 50. The limitation of Applicant's claim requires that the syringe barrel handle member be molded or formed on the rearward end terminus of the syringe barrel. Neither the reference nor the Figures of Osborn, III et al. recite or show a plunger shaft handle member *molded to or formed on* the rearward end *terminus* of a syringe barrel. Accordingly, the Examiner is requested to withdraw this rejection.

- **Specifically regarding the rejection of claim 17:**

Claim 17 has been canceled. The limitations of claim 17 are now included in claim 1.

- **Specifically regarding the rejection of claim 21:**

The rejection of claim 21 should be withdrawn for the reasons stated above with respect to claim 1, as claim 21 depends directly from claim 1.

- **Specifically regarding the rejection of claim 23:**

The rejection of claim 23 should be withdrawn because the Osborn, III et al. reference does not recite using a syringe barrel, plunger shaft, and corrugated sheath that is colored or tinted, as claimed by Applicant. It is unclear how the claim limitations are met by the Osborn, III et al. reference and what teaching in the reference that the Examiner is relying on to meet the limitations. A claim is anticipated by a reference only if each and every element as set forth in the claim is found in the reference. Because the Osborn, III et al. reference is deficient for the reasons advanced above, the Osborn, III et al. reference does not anticipate the limitations of claim 23. Accordingly, the Examiner is requested to withdraw this rejection.

- **Specifically regarding the rejection of claim 24:**

The rejection of claim 24 should be withdrawn because the Osborn, III et al. reference does not recite a removable closure cap, as claimed by Applicant. In fact, there is no motivation nor would there be a reason to provide a removable closure cap. The tampon-dispensing device of Osborn, III et al. is designed to maintain a sealed gas inside the device. A removable closure cap, as recited in Applicant's claim 24, used in Osborn's tampon dispensing device would release the sealed gas if removed. It is unclear how the Osborn, III et al. reference meets the limitations of claim 24. A claim is anticipated by a reference only if each and every element as set forth in the claim is found in the reference. The Osborn, III et al. reference does not anticipate the limitations of claim 24. Accordingly, the Examiner is requested to withdraw this rejection.

- **Specifically regarding the rejection of claim 25:**

The rejection of claim 25 should be withdrawn because the Osborn, III et al. reference does not recite a removably attachable needle or permanently attached needle, as claimed by Applicant. In fact, there is no motivation nor would there be a reason to provide a removably attachable needle or provide the tampon-dispensing device with a permanently attached needle. It is unclear how the claimed limitations are met by the reference and what teaching in the reference that the Examiner is relying on to meet the limitations. A claim is anticipated by a reference only if each and every element as set forth in the claim is found in the reference. The Osborn, III

et al. reference does not anticipate the limitations of claim 25. Accordingly, the Examiner is requested to withdraw this rejection.

- **Specifically regarding the rejection of claim 26:**

The rejection of claim 26 should be withdrawn because the Osborn, III et al. reference does not recite a brace means, as claimed by applicant. The brace means of the instant invention functions to maintain the plunger shaft in a withdrawn position such that the substance in the syringe is not expelled or ejected from the syringe barrel. The brace means restricts the plunger member from movement along and within the syringe barrel until the brace means is removed. It is unclear how the claimed limitations are met by the Osborn, III et al. reference, and what teaching in the reference that the Examiner is relying on to meet the limitation. A claim is anticipated by a reference only if each and every element as set forth in the claim is found in the reference. The Osborn, III et al. reference does not anticipate the limitations of claim 26. Accordingly, the Examiner is requested to withdraw this rejection.

2. Claims 1, 4, 7, 8, 13, 15-17, and 21-26 have been rejected under 35 U.S.C. 102(e) as being anticipated by Park, Patent No. 6,475,193.

- **Specifically regarding the rejection of claim 1:**

Claim 1 has been amended to recite that the syringe has a syringe barrel handle member permanently attached to the syringe barrel rearward end terminus. Also, claim 1 has been amended to recite that the corrugated sheath is attached to a forward face surface of a plunger shaft handle member and a rearward face surface of said permanently attached syringe barrel handle member. The Park reference does not disclose a corrugated sheath attached to a forward face surface of a plunger shaft handle member and a rearward face surface of a syringe barrel handle member that is permanently attached to the rearward end terminus of the syringe barrel. The Examiner noted in the rejection that the bellows in the Park reference is molded to the plunger handle member. However, this is not accurate. Note that the forward end of the bellows 86 of the Park reference is “fixed” to the stopper 80 and the opposite end of the bellows 86 is “hooked” in a groove 76b (see Park reference: column 4, lines 63-67). “Fixing” and “hooking” are not molding. Note that the

stopper 80 can be moved (see column 4, lines 50-53; column 5, lines 46-48) and is not a plunger handle member and is not permanently attached to the rearward end terminus of the syringe barrel. Note also that the bellows 86 is not attached to a syringe barrel handle member. For these reasons, Applicant submits that the Park reference does not anticipate the claimed subject matter of claim 1. A claim is anticipated by a reference only if each and every element as set forth in the claim is found in the reference. Accordingly, the Examiner is requested to withdraw this rejection.

- **Specifically regarding the rejection of claim 4:**

Claim 4 has been cancelled, the limitations of which are now included in claim 1.

- **Specifically regarding the rejection of claim 7:**

Claim 7 has been amended to depend from claim 1. The rejection of claim 7 should be withdrawn because the Park reference does not teach that the plunger shaft handle member is molded to the rear terminus of the plunger shaft, as claimed by Applicant. There is no discussion of an attachment relationship between the grasping portion 76 and the rod 72, or even if an attachment is present. Accordingly, the examiner is requested to withdraw this rejection.

- **Specifically regarding the rejection of claim 8:**

Claim 8 recites that the rear terminus of the corrugated sheath is *molded* the plunger shaft handle member. The Examiner will note that the Park reference discusses at column 4, lines 63-67, with reference to Figure 4, that the bellows 86 is “fixed” to the stopper 80 and the opposite end of the bellows 86 is “hooked” in the groove 76b. “Fixing” and “hooking” are not molding. Further, stopper 80 is not a syringe barrel handle member. Therefore, the Park reference teaches a bellows attached to a stopper and not to a syringe barrel handle member. The limitation of claim 8 is a clear structural difference between claim 8 and the Park reference. A claim is anticipated by a reference only if each and every element as set forth in the claim is found in the reference. The Park reference does not anticipate the limitations of claim 8. Accordingly, the Examiner is requested to withdraw this rejection.

- **Specifically regarding the rejection of claim 13:**

The rejection of claim 13 should be withdrawn for the reasons stated above with respect to claim 1, as claim 13 depends directly from claim 1.

- **Specifically regarding the rejection of claim 15:**

Claim 15 has been cancelled, the limitations of which are now included in claim 1.

- **Specifically regarding the rejection of claim 16:**

Claim 16 has been amended to depend from claim 1. The rejection of claim 16 should be withdrawn because the Park reference does not recite that the syringe barrel handle member is molded to or formed on the rearward end terminus of the syringe barrel, as claimed by Applicant. Note that the limitations of Applicant's claim 16 require that the syringe barrel handle member be molded to or formed on the rearward end terminus of the syringe barrel. This is a clear structural difference between Applicant's claim and the Park reference. A claim is anticipated by a reference only if each and every element as set forth in the claim is found in the reference. The Park reference does not anticipate the limitations of claim 16 or the combination of claims 1 and 16. Accordingly, the Examiner is requested to withdraw this rejection.

- **Specifically regarding the rejection of claim 21:**

The rejection of claim 21 should be withdrawn for the reasons stated above with respect to claim 1, as claim 21 depends directly from claim 1.

- **Specifically regarding the rejection of claim 22:**

The rejection of claim 22 over Park should be withdrawn for the reasons stated above with respect to claim 1, as claim 22 depends directly from claim 1.

- **Specifically regarding the rejection of claim 23:**

The rejection of claim 23 should be withdrawn because the Park reference does not recite using a syringe barrel, plunger shaft, and corrugated sheath that is colored or tinted, as claimed by Applicant. It is unclear how the claim limitations are met by

the Park reference and what teaching in the reference the Examiner is relying on to meet the limitation. A claim is anticipated by a reference only if each and every element as set forth in the claim is found in the reference. The Park reference does not anticipate the limitations of claim 23. Accordingly, the Examiner is requested to withdraw this rejection.

- **Specifically regarding the rejection of claim 24:**

The rejection of claim 24 should be withdrawn because the Park reference does not recite a removable closure cap, as claimed by Applicant. It is unclear how the Park reference is being used to meet the limitations of claim 24. A claim is anticipated by a reference only if each and every element as set forth in the claim is found in the reference. The Park reference does not anticipate the limitations of claim 24. Accordingly, the Examiner is requested to withdraw this rejection.

- **Specifically regarding the rejection of claim 25:**

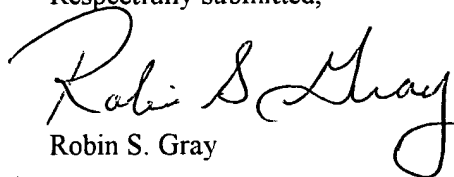
The rejection of claim 25 over Park should be withdrawn for the reasons stated above with respect to claim 1, as claim 25 depends directly from claim 1.

- **Specifically regarding the rejection of claim 26:**

The rejection of claim 26 should be withdrawn because the Park reference does not recite a brace means, as claimed by Applicant. The brace means of the instant invention functions to maintain the plunger shaft in a withdrawn position such that the substance in the syringe is not expelled or ejected from the syringe barrel. The brace means restricts the plunger member from movement along and within the syringe barrel until the brace means is removed. It is unclear how the claimed limitations are met by the Park reference, and what teaching in the reference that the Examiner is relying on to meet the limitation. A claim is anticipated by a reference only if each and every element as set forth in the claim is found in the reference. The Park reference does not anticipate the limitations of claim 26. Accordingly, the Examiner is requested to withdraw this rejection.

New claims 27-32 have been added. The subject matter of the new claims and the amendments is fully supported by the original disclosure and no new matter is added. Support for the subject matter of the new claims and amendments can be found throughout the Specification, Abstract, and Figures – in particular at pages 4-7, 27-31, 34-39, and 66-69. Applicant respectfully submits that the above amendments and/or arguments place the application for patent in condition for allowance and early notification to that effect is respectfully requested.

Respectfully submitted,



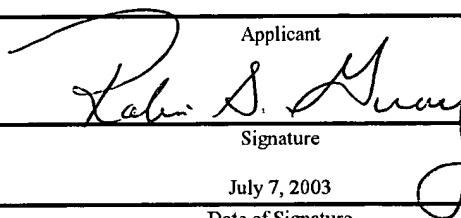
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I hereby certify that this correspondence is being deposited with the United States Postal Service as Post Office To Addressee with Express mail label Number: ET542169350US addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria Virginia 22313-1450, on July 7, 2003.

Robin S. Gray

Applicant



Signature

July 7, 2003

Date of Signature